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Subject: DBE HPV Final Submission - Cover Letter and Response to EPA's Comments

November 8, 2002

Christine Todd Whitman, Administrator
U.S.Environmental Protection Agency
Post Office Box 1473
Merrifield, VA22116

Attn: Chemical Right-to-Know Program; HPV Reference Number:

The Synthetic Organic Chemical Manufacturers Association's (SOCMA) Dibasic Esters (DBE) Group is responding within the allotted 60 days to EPA's comments on our robust summaries and test plan for the dibasic esters category. The EPA's comments and questions were contained in a letter to the DBE Group from Mr. Oscar Hernandez, Director, RiskAssessment Division, dated September 4, 2002. The DBE category represents three dibasic esters: Dimethyl Succinate (DMS, CAS # 106-65-0), Dimethyl Glutarate (DMG, CAS # 1119-40-0), Dimethyl Adipate (DMA, CAS # 627-93-0), and mixtures of these three compounds. The HPV Challenge DBE robust summaries and test plan were posted for public comment on the ChemRTK HPV Challenge Program Website on January 30, 2002.

The edited and enclosed final HPV document is a compilation of five individual documents: Justification of the Dibasic Esters (DBE) Category and Overview of DBE Robust Summaries; Robust Summaries for Dibasic Esters Solvents: Dimethyl Succinate DMS; Robust Summaries for Dibasic Esters Solvents: Dimethyl Glutamate DMG; Robust Summaries for Dibasic Esters Solvents: Dimethyl Adipate DMA; and Robust Summaries for Dibasic Esters Solvents: Dibasic Ester Mixture. This document differs from the one submitted to the EPA on December 31, 2001, in that it contains the following changes to the robust summaries, category development, and test plan:

Ø Superscripts denoting measured and calculated values have been added to Table 1 of the ***Justification of Dibasic Esters (DBE) Category and Overview of DBE Robust Summaries*** as clarification.

Ø The DBE Group does not feel that there would be any benefit in conducting additional studies with fish and the sacrifice of additional animals in further fish studies is not justified based on the available data. The toxicity is consistently, slightly topractically nontoxic for all three esters and the mixture. Toxicity would not be estimated to vary significantly at exposure levels below 18 mg/L or over 100 mg/L. The lowest value or range (18 mg/L) should be used as a conservative estimate of DBE toxicity to fish.

v In addition, there was some confusion about the amount of acetone in the test system. The ratio of 0.1 ml/ml (acetone to water) was the ratio of acetone to water in the stock solution used to prepare the aqueous exposures and does not represent the ambient concentration in the test system. This was clarified in the robust summaries and was corroborated by review of the raw data.

Ø The EPA expressed the need for specific supporting data missing from the robust summary for biodegradation study HLR No. 698-82. The following data are provided:

v The microbial inoculum was a combination of materials from three sources: Wilmington, Delawaresecondary sewage treatment plant, filtrate from 300g of forest soil, and inoculum from continually mixed microbial culture maintained in a biological digester. Theseindividual inoculum were combined in proportions of 4:2:1, respectively.

v Nominal concentrations at initiation were 5 and 10mg C/L and exhibited a degradation half-life of 2.5 days. The study included two external positive controls: Proxel® and linear alkyl sulphonates (LAS) which showed less degradation in a comparable system compared to DBE. In this case, 36% of the theoretical cumulative CO_2 was respired by the mixed microbial system during the study period.

Ø The Daphnia study for DBE (Monsanto 1992) was reviewed and additional data was added to the robust summary including: test material was DME (lot # 192002) and additional data can be found in Lab Book # 4355288.The test material data on nominal and measured concentrations of DME in solution, pH (6.8 – 8.5) and D.O.= >4 ppm. This information as been added the robust summary.

The acute fish study with DMG (HLR No. 679-76) was conducted under static conditions. DMG concentrations and water quality parameters were added to the robust summary.

In addition to the EPA's comments found in Mr. Hernandez' letter, the EPA recommended that both *Daphnia* and Algae toxicity studies be done on DMA to clarify the ecological effects and help interpret the DBE data for read-across purposes. Although the DBE Group does not totally agree with EPA's scientific reasoning, we agree to carry out both *Daphnia* and Algae toxicity studies using DMA. These studies will be carried out in 2003 and reported to the EPA upon completion.

With these additional comments and clarifications made in response to EPA's questions and remarks, resubmission of the edited final HPV document and upon completion of the *Daphnia* and Algae toxicity studies, the DBE Group will have met its obligation in the EPA HPV Challenge Program.

Please contact me at (202) 721-4145 if there are any questions relating to this submission.

Sincerely,

Edward W. Kordoski, MBA, Ph.D.

Executive Director

cc: DBE Group

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[IMAGE]

- DBE HPV Final Submission - DMS Robust Summaries 11-8-2002.doc
- DBE HPV Final Submission - DBE Category Justification and Robust Summaries 11-8-2002.doc
- DBE HPV Final Submission - DBE Mixture Robust Summaries 11-8-2002.doc
- DBE HPV Final Submission - DMA Robust Summaries 11-8-2002.doc
- DBE HPV Final Submission - DMG Robust Summaries 11-8-2002.doc